ROTOP - DMSA - kit for the preparation of technetium tc99m succimer injection injection, powder, lyophilized, for solution
ROTOP Pharmaka GmbH

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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ROTOP – DMSA

August 3, 2017

Subject: Temporary importation of Kit for the Preparation of Technetium Tc99m Succimer Injection to address drug shortage issues

Dear Healthcare Professional,

Due to the current critical shortage of DMSA Kit for the Preparation of Technetium Tc99m Succimer, Theragnostics Inc. (Theragnostics) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug. Theragnostics has initiated temporary importation of DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection into the U.S. market. This product is marketed in Germany and is manufactured in Dresden, Germany by ROTOP Pharmaka GmbH for Theragnostics.

At this time, no other entity except ROTOP Pharmaka GmbH, Germany through its distributor, Theragnostics, is authorized by the FDA to import or distribute the DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection in the U.S. FDA has not approved ROTOP Pharmaka GmbH’s Kit for DMSA Preparation of Technetium Tc99m Succimer Injection product in the U.S.

Effective immediately, and during this temporary period, Theragnostics will offer the following presentation of ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection:

<table>
<thead>
<tr>
<th>Product</th>
<th>Strength</th>
<th>Size</th>
<th>Marketing Authorization #</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROTOP DMSA (Kit for the Preparation of Technetium Tc99m Succimer Injection)</td>
<td>One vial contains 1.74 mg powder with the active substance: 1.0 mg succimer</td>
<td>5 vials in a carton</td>
<td>3003663.00.00 Germany (NDC 71647-001-01)</td>
</tr>
</tbody>
</table>

The vial and carton labels will display the text, translated to English, as approved via the Marketing Authorization of EEA in Germany. At the end of this letter you will find a product comparison table with the prescribing information in English, as well as images of the labels for your reference.

There are some differences in the labeling between the FDA-approved DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection (GE Healthcare) product and ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection (Theragnostics) product (please see the product comparison tables below). These differences do not alter the favorable risk/benefit of the drug:

- In alignment with current practice, the ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer label does not include a statement under the heading “Pediatric Use” that appears in the GE Healthcare label as follows: “Safety and effectiveness in pediatric patients have not been established.”
- Unlike the GE Healthcare label, the ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer label contains pediatric dosing information under the heading “How to Use ROTOP DMSA”. Pediatric doses can also be calculated online through the Society of Nuclear Medicine and Molecular Imaging website’s Pediatric Injected Activity Tool.
The ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer label does not state the product is sterile; however, like the GE Healthcare product, ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer is manufactured to be sterile.

Side effects encountered with use of the ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer within the U.S. can be reported directly to Theragnostics, Inc., at 1-888-286-3848 rather than the foreign site referenced in the label for ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer.

ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection is available only by prescription in the U.S.

Please refer to the package insert for the FDA-approved DMSA Kit for the Preparation of Technetium Tc99m Succimer drug product for full prescribing information.

ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection (Theragnostics) does not contain a barcode. Institutions should manually input the product into their systems. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

To place an order, or if you have any questions about the information contained in this letter or the use of ROTOP DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection (Theragnostics), please contact Theragnostics, Inc., Boston, Massachusetts, 1-617-286-7479, 9:00 AM to 5:00 PM Eastern time.

To report adverse events or quality problems associated with the use of this product, please call Theragnostics, Inc., Boston, Massachusetts, 1-888-286-3848

CONTACT NUMBERS: Please use the following contact numbers as appropriate:

Phone: 1-617-286-7479
Fax: 1-617-398-6337

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Sincerely,

Patrick J. Donahue
President & CEO

Patient Package Insert

This Package Leaflet and Summary of Product Characteristics was translated by the manufacturer based on the original German document (Vs. 4), authorized by the German Federal Institute for Drugs and Medicinal Services in November 2014.

Package Leaflet and Summary of Product Characteristics

**ROTOP - DMSA, 1.0 mg**
Kit for radiopharmaceutical preparation
Succimer

Read all of this information carefully before you start using this medicine
- Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What ROTOP – DMSA is and what it is used for
2. Before you use ROTOP – DMSA
3. How to use ROTOP – DMSA
4. Possible side effects
5. How to store ROTOP – DMSA
6. Further information

1. WHAT ROTOP-DMSA IS AND WHAT IT IS USED FOR

ROTOP - DMSA is a radiodiagnostic pharmaceutical. The kit contains the non-radioactive powder for reconstitution of the $[^{99m}Tc]$technetium succimer injection solution ($[^{99m}Tc]$-DMSA). The sodium $[^{99m}Tc]$pertechnetat which is needed for the preparation is not part of this kit.

After labelling with sodium $[^{99m}Tc]$technetium pertechnetat solution, ROTOP - DMSA is used for static renal scintigraphy when adequate diagnostics are not possible using other diagnostic procedures (such as ultrasound):
- to identify focal renal parenchymal changes (e.g. in the case of renal infarction)
- to identify norm variants such as atypical double kidney, small kidney, dysplastic kidney, horseshoe kidney, as well as to identify ectopic kidneys
- to confirm absence of renal function in multicystic kidneys.

2. BEFORE YOU USE ROTOP - DMSA

Take special care with ROTOP – DMSA

ROTOP - DMSA is not suitable for determining global renal function from the DMSA accumulation. In the case of proximal tubulopathies $[^{99m}Tc]$DMSA does not lead to a sufficient diagnostic renal accumulation.

The patient must be well hydrated before and after administration. In order to keep radiation exposure to a minimum, patients must be encouraged to empty their bladders as often as possible during the first hours after the examination.

For each patient it should be carefully considered whether the expected diagnostic benefits outweigh the risk linked to radiation exposure. In order to keep the radiation dose as low as possible, the administered activity may not be higher than that required for eliciting the diagnostic information.

Radiopharmaceuticals may be received, used and administered only by authorised persons in areas specially designated for this purpose. The manipulation and use of these products is subject to the regulations of the local supervisory authority and/or requires appropriate permission.

Using other medicines

Chemotherapeutic agents such as methotrexate, cyclophosphamide and vincristine can alter the biodistribution of $[^{99m}Tc]$DMSA.
Shifting the acid/base balance, e.g. through ammonium chloride or sodium hydrogen carbonate, effects in vivo a change in the valence of the $[^{99}\text{Tc}]\text{DMSA}$ complex and in turn a lower accumulation in the renal cortex with simultaneous strong accumulation in the liver and rapid urine excretion. Mannitol leads to dehydration and in turn to a reduction in the extraction of $[^{99}\text{Tc}]\text{DMSA}$.

In the case of renal artery stenosis, ACE inhibitors can lead to a reversible insufficiency of the tubular function and in turn to a reduced accumulation of $[^{99}\text{Tc}]\text{DMSA}$ as a result of the reduction in filtration pressure in the affected kidney.

If high doses of other chelating agents are injected at the same time, the stability of the $[^{99}\text{Tc}]\text{DMSA}$ may be influenced, thus effecting a change in kinetics.

**Pregnancy and lactation**

**Pregnancy:** No data on the clinical use of $[^{99}\text{Tc}]\text{DMSA}$ with pregnant women is available. If it is necessary to administer a radiopharmaceutical product to a woman of child-bearing age, she must have a pregnancy test first.

If a woman has missed a period, it must be assumed that she is pregnant. In case of doubt, radiation exposure must be reduced to the minimum amount required to acquire the needed clinical information. In this case, alternative investigative methods must be considered that do not use ionising radiation. Radiopharmaceutical examinations of pregnant women also expose the foetus to radiation. For this reason, $[^{99}\text{Tc}]\text{DMSA}$ may only be used if there is a vital indication and if the expected benefit outweighs the risk to mother and child.

**Lactation:** Before administering $[^{99}\text{Tc}]\text{DMSA}$ to a breast-feeding mother, it must be considered whether the investigation could also be delayed until the mother has ceased breast-feeding and as to whether using a radiopharmaceutical is the most appropriate examination method, bearing in mind the secretion of activity into breast milk. If administering $[^{99}\text{Tc}]\text{DMSA}$ is deemed necessary, breast-feeding must be interrupted for at least 12 hours, and the expressed breast milk discarded.

**Driving and using machines**

Effects on the ability to drive or use machines have not been described.

**Precautions for avoiding hazards for the environment**

Radiopharmaceuticals must be prepared and used by the user under precautions for the protection from ionizing radiation and taking pharmaceutical quality standards into account. In accordance with the guidelines for Good Pharmaceutical Manufacturing Practice, work must be done under aseptic conditions.

Patients treated with radiopharmaceuticals pose a risk for other persons based on external radiation exposure or contamination due to spilling urine, vomiting, etc. For this reason, the precautionary measures provided by the national radiation protection regulations must be observed. Contamination brought about by radioactivity that has been excreted by the patient must be avoided.

**3. HOW TO USE ROTOP - DMSA**

Single intravenous use after preparation with sodium $[^{99}\text{Tc}]\text{pertechnetate}$ solution.

Adults are given 0.3 to 1.0 mg succimer and activities of 70 MBq.

Scintigraphic examinations should not be carried out until at least 1 hour after application; waiting 3 hours is preferable. In the case of very poor renal function, waiting periods of up to 6 hours should be observed. The patient must be well hydrated.

**Children**

The recommendation of the Paediatric Task Group of the European Association of Nuclear Medicine (EANM) of 1990 lists the paediatric dose scaled to body weight as a fraction of the adult dose:
Activity of less than 20 % (15 MBq) of the adult dose generally does not allow a satisfactory assessment to be derived from the examination.

If you use more ROTOP – DMSA than you should

Due to the low amounts of substances used, overdosage in the pharmacological sense is not expected. Exposure to radiation resulting from an overdosage of radioactivity can be reduced by forced diuresis.

4. POSSIBLE SIDE EFFECTS

As all medicinal products, ROTOP - DMSA can cause side effects, although not everybody gets them.

For assessing the side effects the frequency is classified as follows:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>observed in more than 1 patients in 10</td>
</tr>
<tr>
<td>Common</td>
<td>observed in less than 1 patient in 10, but more than 1 patient in 100</td>
</tr>
<tr>
<td>Uncommon</td>
<td>observed in less than 1 patient in 100, but more than 1 patient in 1,000</td>
</tr>
<tr>
<td>Rare</td>
<td>observed in less than 1 patient in 1,000, but more than 1 patient in 10,000</td>
</tr>
<tr>
<td>Very rare</td>
<td>observed in less than 1 patient in 10,000 or not known</td>
</tr>
</tbody>
</table>

In very rare cases (< 0.01 %) after intravenous injection of the ready-to-use solution, hypersensitivity reactions have occurred such as locally confined or general rashes, itching, drop in blood pressure, headache, dizziness, nausea and vomiting. Reactions can occur up to 24 hours after the injection.

Although such reactions are very rare and usually very minor, appropriate instruments and medications for immediate treatment of allergic reactions (adrenaline, corticosteroids and antihistamines) should be within reach for possible emergency treatment at all times.

Since the administered amounts of active substances are very low, the risks of use are mainly related to radiation exposure. Ionising radiation can cause cancer and genetic mutations.

Since most radiopharmaceutical examinations are conducted with low effective radiation doses of less than 20 mSv, the probability of such effects occurring is expected to be low.

The effective radiation dose is 0.62 mSv when the maximum recommended activity of this medicinal product is applied.

Reporting of side effects

If you notice any side effects please contact your nuclear physician responsible for supervising the administration. This also applies to any side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ROTOP - DMSA

Keep out of the reach and sight of children.

Do not use this medicinal product after the expiry date stated on the label.

Storage conditions

Store refrigerated (2 to 8 °C) in the original package. Radiopharmaceuticals must be stored in accordance with the regulations for radioactive protection and in particular be kept from unauthorised access.

Shelf life after opening and reconstitution

The product labelled with [99mTc]technetium can be injected within 4 hours after reconstitution and has to be stored at room temperature (15–25 °C) during this time.

6. FURTHER INFORMATION

What ROTOP – DMSA contains

One vial contains 1.74 mg powder with the active substance:
1.0 mg succimer

The other ingredients are:
Stannous chloride dihydrate
Ascorbic acid
Sodium hydroxide
Hydrochloric acid 36%
Nitrogen

What ROTOP – DMSA looks like and contents of the pack:

The package consists of a carton with 5 vials.

Marketing Authorisation Holder and Manufacturer

ROTOP Pharmaka GmbH,
Bautzner Landstr. 400,
01328 Dresden,
Germany
Tel: 0049 + (0) 351 – 26 310 210
Fax: 0049 + (0) 351 – 26 310 313
e-mail: service@rotop-pharmaka.de

This medicinal product is authorised in the Member States of the EEA under the following names:
Germany: ROTOP - DMSA

This leaflet was last approved in November 2014.

The following information is intended for medical or healthcare professionals only:

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
Pharmacotherapeutic group: Diagnostic radiopharmaceutical for renal diagnostics (ATC: V09CA02).
Based on current research, for the low amounts of substances used for imaging techniques no clinically relevant pharmacodynamic effects of $[^{99m}Tc]$DMSA are expected.

**Pharmacokinetic properties**
After intravenous injection, within 5 minutes over 70% of the $[^{99m}Tc]$DMSA is bound to the α-2 microglobulin fraction in blood plasma. Binding to erythrocytes may be disregarded. One hour post injection, 25% of the radiopharmaceutical is already located in the renal cortex and only 30% remains in the plasma. Approx. 10% appears in the urine.

In healthy persons, the plasma clearance of $[^{99m}Tc]$DMSA amounts to approx. 10 ml/min. (scaled to 1.73 sqm body surface). After approx. 3 hours, the maximum renal accumulation is reached. In healthy persons, at this point approx. 50% of the radiopharmaceutical is located in the renal cortex, approx. 20% remains in the plasma and just under 10% in the liver and muscles. Within 24 hours, approx. 30% is excreted with the urine.

$[^{99m}Tc]$DMSA accumulates in the pars recta and convoluta of the proximal renal tubules – most likely due to peritubular reabsorption. On an intracellular level, the majority of the $[^{99m}Tc]$DMSA is bound to a soluble protein in the cytosol. This mechanism, which has not yet been explained in detail, is disrupted in the case of proximal tubulopathies (such as nephritides or the Fanconi syndrome), which can be recognised by the increased plasma clearance of $[^{99m}Tc]$DMSA and low renal accumulation.

**Toxicological properties**
Due to the low amounts of DMSA and stannous chloride contained in the kit, toxic effects brought about by the substances are not expected if used according to directions. Data on investigations on reproduction toxicity as well as on mutagenicity and cancerogenity are not available.

**Special precautions for disposal and further directions for handling**
The empty package is considered to be regular waste if the permitted level for $[^{99m}Tc]$technetium is not exceeded (≤ 0.5 Bq/g or 0.5 Bq/cm$^2$). Particulars indicating radioactivity must be removed prior to disposing of the non-radioactive waste and must be destroyed separately. Radioactive waste must be disposed of as provided by law.

**MARKETING AUTHORISATION NUMBER**
3003663.00.00

**DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
24/11/2005

**DOSIMETRY**

**Radiation exposure**
According ICRP publication 80 (Table 1) the following radiation doses will be absorbed:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Adults</th>
<th>15 years</th>
<th>10 years</th>
<th>5 years</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenals</td>
<td>0.012</td>
<td>0.016</td>
<td>0.024</td>
<td>0.035</td>
<td>0.060</td>
</tr>
<tr>
<td>Bladders wall</td>
<td>0.018</td>
<td>0.023</td>
<td>0.029</td>
<td>0.031</td>
<td>0.057</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.0050</td>
<td>0.0062</td>
<td>0.0092</td>
<td>0.014</td>
<td>0.026</td>
</tr>
<tr>
<td>Brain</td>
<td>0.0012</td>
<td>0.0015</td>
<td>0.0025</td>
<td>0.0040</td>
<td>0.0072</td>
</tr>
<tr>
<td>Breast</td>
<td>0.0013</td>
<td>0.0018</td>
<td>0.0028</td>
<td>0.0045</td>
<td>0.0084</td>
</tr>
<tr>
<td>Gall bladder</td>
<td>0.0083</td>
<td>0.010</td>
<td>0.014</td>
<td>0.022</td>
<td>0.031</td>
</tr>
<tr>
<td>Stomach wall</td>
<td>0.0052</td>
<td>0.0063</td>
<td>0.010</td>
<td>0.014</td>
<td>0.020</td>
</tr>
<tr>
<td>Colon</td>
<td>0.0050</td>
<td>0.0063</td>
<td>0.010</td>
<td>0.014</td>
<td>0.024</td>
</tr>
<tr>
<td>Intestine</td>
<td>0.0043</td>
<td>0.0055</td>
<td>0.0082</td>
<td>0.012</td>
<td>0.020</td>
</tr>
</tbody>
</table>
In an adult (70 kg), after intravenous injection of 70 MBq (maximum dose) $^{99m}\text{Tc}$DMSA, the effective dose is approx. 0.62 mSv. The absorbed dose in the target organ kidney is approx. 12.6 mGy and in the critical organ bladder wall 1.26 mGy.

**Radiophysical Properties**

$^{99m}\text{Tc}$technetium is produced using a $^{99}\text{Mo}/^{99m}\text{Tc}$ sterile generator and decays releasing gamma radiation with an energy of 140/142 keV with a half-life of 6.02 hours to $^{99}\text{Tc}$technetium, which in turn decays to stable $^{99}\text{Ru}$ruthenium; However, due to a long half-life of 214,000 years, $^{99}\text{Tc}$ itself is considered to be stable.

**INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS**

**Instruction for labelling**

$^{99m}\text{Tc}$technetium succimer injection solution is prepared under sterile conditions with a sodium $^{99m}\text{Tc}$pertechnetate injection solution (European Pharmacopoeia quality 4.00/0124 or 4.00/0283) directly before use. Oxygenation must be avoided.

Place the vial with powder in sufficient lead shielding with ample space and disinfect the stopper (allow disinfectant to dry). Use a syringe with the smallest possible cannula lumen to transfer 5 mL sodium $^{99m}\text{Tc}$technetium pertechnetate solution with a maximum of 3 GBq to the vial. Use the same syringe to withdraw the appropriate gas volume from the vial for pressure compensation.

lightly shake the vial in order to completely dissolve the powder. The stopper should be well moistened as well. After 10 minutes reaction time, measure the overall activity. If needed, the finished injection solution can be diluted with sterile isotonic sodium chloride to a total volume of up to 10 mL.

**Quality Control**

Prior to use in the patient, the radiochemical purity of the $^{99m}\text{Tc}$technetium succimer injection solution must be tested using the method described below:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Activity (MBq)</th>
<th>Effective Dose per unit of activity administered (mSv/MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper large intestine</td>
<td>0.0050</td>
<td>0.0088</td>
</tr>
<tr>
<td>Lower large intestine</td>
<td>0.0035</td>
<td>0.0011</td>
</tr>
<tr>
<td>Heart</td>
<td>0.0030</td>
<td>0.0015</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.014</td>
<td>0.021</td>
</tr>
<tr>
<td>Liver</td>
<td>0.0050</td>
<td>0.0045</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.0250</td>
<td>0.0077</td>
</tr>
<tr>
<td>Muscles</td>
<td>0.0029</td>
<td>0.0061</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>0.0035</td>
<td>0.0053</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.0090</td>
<td>0.0083</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.0039</td>
<td>0.0056</td>
</tr>
<tr>
<td>Red marrow</td>
<td>0.0015</td>
<td>0.0045</td>
</tr>
<tr>
<td>Skin</td>
<td>0.0130</td>
<td>0.0018</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.0018</td>
<td>0.0024</td>
</tr>
<tr>
<td>Testes</td>
<td>0.0017</td>
<td>0.0023</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.0045</td>
<td>0.0056</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.0029</td>
<td>0.0037</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.0045</td>
<td>0.0056</td>
</tr>
<tr>
<td>Remaining organ</td>
<td>0.0029</td>
<td>0.0037</td>
</tr>
</tbody>
</table>
Preparation:
Type of test: Thin layer chromatography
Plates used: Silica gel on a glass fibre plate, heated for 10 min. at 110°C prior to testing
Starting point: 1.5 cm from lower end of the plate
Migration distance: 10 to 15 cm (in approx. 15 minutes)

Execution:
Use a capillary tube or pipette to extract a volume of approx. 5 μl and apply it to the plate.
Chromatography begins immediately with a solution of sodium chloride (9 g/L) over a migration distance of 10 to 15 cm. Allow the plate to air-dry, and use a detector to determine the distribution of radioactivity.

Evaluation:
\[ ^{99m}\text{Tc} \]technetium in colloidal form remains at the starting point, and the \[ ^{99m}\text{Tc} \]technetium succimer complex migrates to nearly the middle of the chromatogram.
Target value: ≤ 2.0% \[ ^{99m}\text{Tc} \]pertechnetate

CLASSIFICATION FOR SUPPLY
Pharmacy-only medicine

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL
**Product Information**

**Product Type**: HUMAN PRESCRIPTION DRUG

**Item Code (Source)**: NDC:71647-001

**Route of Administration**: INTRAVENOUS

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,3-DIMERCAPTOSUCCINIC ACID</td>
<td>2,3-DIMERCAPTOSUCCINIC ACID</td>
<td>1 mg</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**
<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANNOUS CHLORIDE (UNII: 1BQV3749L5)</td>
<td></td>
</tr>
<tr>
<td>ASCORBIC ACID (UNII: PQ6CK8PD0R)</td>
<td></td>
</tr>
<tr>
<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
<td></td>
</tr>
<tr>
<td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td>
<td></td>
</tr>
<tr>
<td>NITROGEN (UNII: N762921K75)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:71647-001-01</td>
<td>5 in 1 CARTON</td>
<td>08/08/2017</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1 in 1 VIAL; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unapproved drug for use in drug shortage</td>
<td></td>
<td>08/08/2017</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler** - ROTOP Pharmaka GmbH (314666202)

**Registrant** - Theragnostics Inc. (080437847)

**Establishment**

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<th>Address</th>
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<td>314666202</td>
<td>MANUFACTURE(71647-001)</td>
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Revised: 8/2017